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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
07/565,673	08/10/1990	JOHANNES C. VAN DER LAAN		8222

7590 08/12/2005

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EXAMINER	
FRONDA, CHRISTIAN L	
ART UNIT	**PAPER NUMBER**
1652	

DATE MAILED: 08/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	07/565,673	VAN DER LAAN ET AL.	
	Examiner	Art Unit	
	Christian L. Fronda	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on 2/01/2005.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 48,50,53 and 54 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 48,50,53 and 54 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. The finality of the Office Action dated 12/01/2004 has been withdrawn. New rejections and additional grounds of rejection are presented below.

2. Claims 48, 50, 53, and 54 are pending and under consideration in this Office Action.

Claim Rejections - 35 U.S.C. § 112, 2nd Paragraph

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 48, 50, 53, and 54 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 48 is vague and indefinite because the claim recites homolgous recombination with a "wild-type alkaline serine protease" but line 13 recites "inactivated wild-type Bacillus PB92 extracellular serine protease". The metes and bounds of the claim are not certain since it is not clear if the inactivated protease is the first recited "alkaline serine protease". Appropriate correction is requested.

Claims 50 and 54 are vague and indefinite since the claim recites specific positions of amino acid residues of 160, 216, and 212 but there is no specific SEQ ID NO: recited in the claim. The metes and bounds of the claim are not certain since it is not clear what specific amino acid residues are replaced.

Claim Rejections - 35 U.S.C. § 112, 1st Paragraph

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 48, 50, 53, and 54 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for the following additional reasons.

In the evaluation of the claims for compliance with the written description requirement of 35 U.S.C. 112, of particular relevance is 66 FR 1099, Friday, January 5, 2001,which states:

> "*Eli Lilly* explains that a chemical compound's name does not necessarily convey a written description of the named chemical compound, particularly when a genus of compounds is claimed. *Eli Lilly,* 119 F.3d at 1568, 43 USPQ2d at 1405. The name, if it does no more than distinguish the claimed genus from all others by function, does not satisfy the written description requirement because "it does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. *Eli Lilly,* 119 F.3d at 1568, 43 USPQ2d at 1406. Thus *Eli Lilly* identified a set of circumstances in which the words of the claim did not, without more, adequately convey to others that applicants had possession of what they claimed." (see p. 1100, 1st column, line 47 to 2nd column, line 2).

The claims are genus claims directed toward several genera: a genus of genes of any nucleotide sequence and structure encoding any wild-type alkaline serine protease of any amino acid sequence and structure; a genus of coding regions of any nucleotide sequence and structure encoding any wild-type alkaline serine protease; a genus of wild-type alkaline serine proteases of any amino acid sequence and structure; a genus of 5' and 3' flanking non-coding regions of any nucleotide sequence and structure of any wild-type alkaline serine protease; a genus of mutant high alkaline serine proteases of any amino acid sequence and structure; and a genus of wild-type high alkaline serine proteases of any amino acid sequence and structure.

The scope of each genus includes many members with widely differing structural, chemical, and physiochemical properties. Furthermore, each genus is highly variable because a significant number of structural differences between genus members exists.

The recitation of the phrases "gene encoding the wild-type alkaline serine protease" and "coding region" does not define any structural features commonly possessed by the claimed genus of genes encoding wild-type alkaline serine proteases nor define any structural features commonly

possessed by the claimed genus of coding regions of any nucleotide sequence and structure encoding any wild-type alkaline serine protease. Recitation of the phrase "wild-type Bacillus PB92 extracellular serine protease" does not define any structural features commonly possessed by members of the genus of wild-type alkaline serine proteases of any amino acid sequence and structure. Recitation of the phrase "5' and 3' flanking non-coding regions" is not disclosure of its nucleotide sequence and structure and does not define any structural features commonly possessed by the claimed genus of 5' and 3' flanking non-coding regions of any nucleotide sequence and structure of any wild-type alkaline serine protease. Furthermore, recitation of the phrase "sufficient amount of said 5' and 3' flanking non-coding regions is present to provide for homologus recombination with the indigenous gene encoding the wild-type alkaline serine protease" is not disclosure of its nucleotide sequence and structure.
Recitation of the phrase "mutant high alkaline serine protease" does not define any structural features commonly possessed by members of the genus of mutant high alkaline serine proteases of any amino acid sequence and structure. Recitation of the phrase "wild-type high alkaline serine protease" does not define any structural features commonly possessed by members of the genus of wild-type high alkaline serine proteases of any amino acid sequence and structure. One skilled in the art therefore cannot visualize or recognize the identity of the members of each genus.

In view of the above considerations, one of skill in the art would not recognize that applicants were in possession of a genus of genes of any nucleotide sequence and structure encoding any wild-type alkaline serine protease of any amino acid sequence and structure; a genus of coding regions of any nucleotide sequence and structure encoding any wild-type alkaline serine protease; a genus of wild-type alkaline serine proteases of any amino acid sequence and structure; a genus of 5' and 3' flanking non-coding regions of any nucleotide sequence and structure of any wild-type alkaline serine protease; a genus of mutant high alkaline serine proteases of any amino acid sequence and structure; and a genus of wild-type high alkaline serine proteases of any amino acid sequence and structure.

Furthermore, a review of the specification and the claims indicates that gene elements which are not particularly described including the promoter, regulatory elements, and 5' and 3' flanking non-coding regions are essential to the function of the claimed invention since the claims recite a gene encoding a Bacillus wild-type alkaline serine protease and the 5' and 3' flanking non-coding regions. The art indicates that the structure of genes elements is empirically determined. Therefore, the structure of these gene elements which applicants considers as being essential to the function of the claim are not conventional in the art.

There is no known or disclosed correlation between the coding region of the wild-type alkaline serine protease and the structure of the non-described promoter, regulatory elements, and

5' and 3' flanking non-coding regions of the gene. There is no additional disclosure of physical and/or chemical properties of these gene elements. In particular there is no disclosure of nucleotide sequence and structure of the 5' and 3' flanking non-coding regions.

In view of the above considerations, one of skill in the art would not recognize that applicants were in possession of the gene elements including promoter, regulatory elements, and 5' and 3' flanking non-coding regions of the Bacillus wild-type alkaline serine protease.

Conclusion

7. No claim is allowed.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christian L Fronda whose telephone number is (571)272-0929. The examiner can normally be reached Monday-Friday between 9:00AM - 5:00PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura N Achutamurthy can be reached on (571)272-0928. The fax phone number for the organization where this application or proceeding is assigned is (571)273-8300.

9. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CLF

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